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PART B: 510(k) SUMMARY

Submitter:

Ascent Healthcare Solutions
10232 South 51st Street
Phoenix, Arizona 85044

Contact:

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SEP - 5 2006

Date of preparation: June 6, 2006

Name of device:

Trade/Proprietary Name: Reprocessed External Fixation Devices
Common or Usual Name: External Fixation Devices, Fixation Appliance, Single/Multiple Component
Classification Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories and Smooth or Threaded Metallic Bone Fixation Fastener

Predicate Device	
510(k) Title	**Manufacturer**
K984357	TRANSFX EXTERNAL FIXATION SYSTEM
K990848	TRANSFX INTERMEDIATE EXTERNAL FIXATION SYSTEM
K991723	TRANSFX MULTI PIN CLAMP IMMEDICA, INC
K001084	TRANSFX ADJUSTABLE PIN TO BAR CLAMP

Device description:

The TransFx™ External Fixation System is a modular system. The system design is designed to provide options in frame construction, simplicity in frame components, and ease of transition from one frame size to another.

Intended use:

Zimmer TransFx External Fixation Devices are intended to be used for fractures of the long bones and pelvis, joint fusion, limb lengthening, osteotomies, and periarticular fractures.

Indications statement:

Zimmer TransFx External Fixation Devices are indicated for fractures of the long bones and pelvis, joint fusion, limb lengthening, osteotomies, and periarticular fractures.

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Technological characteristics:

The design, materials, and intended use of the Reprocessed External Fixation Devices are identical to the predicate devices. The mechanism of action of the Reprocessed External Fixation Device is identical to the predicate devices in that the same standard mechanical design, materials, shapes and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation.

Performance data:

These devices will be provided sterile and non-sterile depending on customer preference.

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of Reprocessed External Fixation Devices. This included the following tests:

- Validation of reprocessing
- Sterilization Validation (for sterile devices)
- Function test(s)

Performance testing demonstrates that Reprocessed External Fixation Devices perform as originally intended.

Conclusion:

Ascent Healthcare Solutions concludes that the modified devices (Reprocessed External Fixation Device) are safe, effective, and substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ascent Healthcare Solutions
% Ms. Amanda Babcock
Regulatory Affairs Specialist
10232 South 51st Street
Phoenix, Arizona 85044

SEP - 5 2006

Re: K061759
Trade/Device Name: Reprocessed Zimmer TransFx™ External Fixation Devices
(See enclosed list)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: June 20, 2006
Received: June 22, 2006

Dear Ms. Babcock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Brennan
for

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Reprocessed Zimmer TransFx™ External Fixation Devices found to be substantially equivalent:

Intermediate 8mm	
Name	**Part Number**
TransFx-Carbon Fiber Rod, 8mmx60mm	4451-08-06
TransFx-Carbon Fiber Rod, 8mmx80mm	4451-08-08
TransFx- Carbon Fiber Rod, 8mm x 100mm	4451-08-10
TransFx- Carbon Fiber Rod, 8mm x 120mm	4451-08-12
TransFx- Carbon Fiber Rod, 8mm x 140mm	4451-08-14
TransFx- Carbon Fiber Rod, 8mm x 160mm	4451-08-16
TransFx-Carbon Fiber Rod, 8mmx180mm	4451-08-18
TransFx-Carbon Fiber Rod, 8mm x 200mm	4451-08-20
TransFx-Carbon Fiber Rod, 8mm x 220mm	4451-08-22
TransFx-Carbon Fiber Rod, 8mm x 240mm	4451-08-24
TransFx- Carbon Fiber Rod, 8mm x 300mm	4451-08-30
TransFx- Carbon Fiber Rod, 8mm x 350mm	4451-08-35
TransFx-Protective Caps, 8mm	4452-92-08
TransFx-Protective Caps, 2.5/3.0mm	4452-92-25
TransFx-Protective Caps, 3./4.0mm	4452-92-35
TransFx-Rod to Rod Clamp 8mm to 8mm	4452-10-08
TransFx-Open Rod to Rod Transitional Clamp 4mm to 8mm	4452-15-48
TransFx-Open Rod to Rod Transitional Clamp, 8mm to 11mm	4452-15-81
TransFx-Open Rod to Rod clamp, 8mm to 8mm	4452-15-88
TransFx-Open Pin to rod Clamp, 2.5 to 4.5mm/8mm	4452-25-28
TransFx-Multi-Pin Clamp, 8mm, Single Connect	4452-30-08
TransFx-Multi-Pin Clamp, 8mm, End Connect	4452-31-08
TransFx-Multi-Pin Clamp, 8mm, Mid Connect	4452-32-08
Large 11mm	
Name	**Part Number**
TransFx-Carbon Fiber Rod, 11mmx100mm	4451-01-10
TransFx-Carbon Fiber Rod, 11mmx125mm	4451-01-12
TransFx-Carbon Fiber Rod, 11mmx150mm	4451-01-15
TransFx-Carbon Fiber Rod, 11mmx200mm	4451-01-20
TransFx-Carbon Fiber Rod, 11mmx250mm	4451-01-25
TransFx- Carbon Fiber Rod, 11mmx300mm	4451-01-30
TransFx-Carbon Fiber Rod, 11mmx350mm	4451-01-35
TransFx-Carbon Fiber Rod, 11mm x 400mm	4451-01-40
TransFx-Carbon Fiber Rod, 11mmx450mm	4451-01-45
TransFx-Carbon Fiber Rod, 11mmx500mm	4451-01-50
TransFx-Carbon Fiber Rod, 11mmx550mm	4451-01-55
TransFx-Carbon Fiber Rod, 11mmx600mm	4451-01-60
TransFx-Carbon Fiber Rod, 11mmx650m	4451-01-65
TransFx-Aluminum Angled Rod, 11mm x 135mm	4451-01-91
TransFx-Aluminum Angled Rod, 11mm x 180mm	4451-01-92
TransFx-Protective Caps, 11mm	4452-92-11
TransFx-Protective Caps, 4.5/5.0mm	4452-92-45
TransFx-Rod to Rod Clamp 11mm to 11mm	4452-10-11

TransFx-Open Rod to Rod Clamp 11mm to 11mm	4452-15-11
TransFx-Open Pin to Rod Clamp, 4.0 to 6.0mm/11mm	4452-25-51
TransFx-Multi-Pin Clamp, 11 mm, Single Connect	4452-30-11
TransFx-Multi-Pin Clamp, 11 mm, End Connect	4452-31-11
TransFx-Multi-Pin Clamp, 11 mm, Mid Connect	4452-32-11
TransFx-Adjustable Clamp, 4.0 to 6.0mm/11 mm	4452-35-51

2. Indications for Use

510(k) Number (if known): K061759

Device Name: Ascent Healthcare Solutions Reprocessed External Fixation Devices

Indications for Use: Zimmer TransFx External Fixation Devices are indicated for fractures of the long bones and pelvis, joint fusion, limb lengthening, osteotomies, and periarticular fractures.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) or Over-the-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061759